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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,376	05/02/2006	Claus Harder	117163.00158	8059

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EXAMINER	
GANESAN, SUBA	

ART UNIT	PAPER NUMBER
3774	

NOTIFICATION DATE	DELIVERY MODE
11/02/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@hahnlaw.com
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Office Action Summary	Application No.	Applicant(s)	
	10/562,376	HARDER ET AL.	
	Examiner	Art Unit	
	Suba Ganesan	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

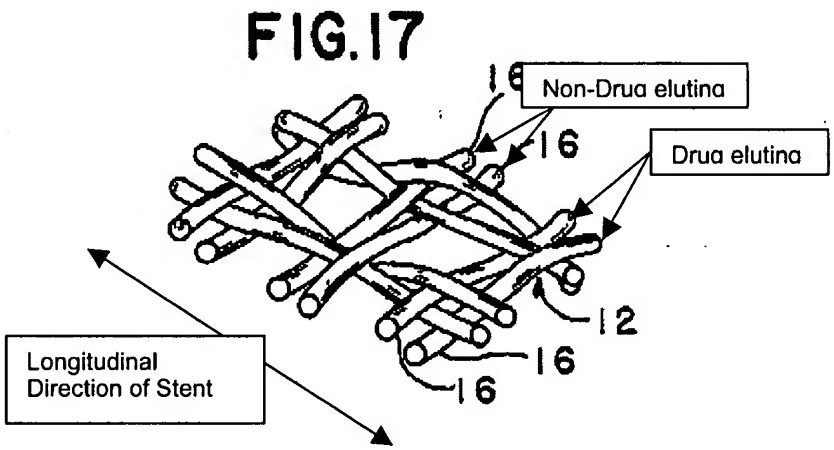
Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 8/21/2007 have been fully considered but they are not persuasive. The applicant argues that the Wolff patent (WO 91/12779) does not provide a variance in drug concentration in the longitudinal direction of the stent. Examiner disagrees, because Wolff discloses weaving non-drug eluting strands with drug eluting strands. Examiner has annotated fig. 17 below as an example:



2. Wolff discloses that filaments can be drug eluting or non-drug eluting (pg. 11 lines 9-26). Because an exemplary longitudinal direction (as shown in the annotated figure) can have certain filaments that are drug eluting filaments as well as non-drug eluting filaments, the local elution characteristics of the stent of Wolff are altered in the longitudinal direction.

3. Wolff further provides for varied elution that occurs along the longitudinal direction with parallel *longitudinal* fibers that are eluting and non-eluting. The overall structure of Wolff is woven (as seen in annotated fig. 1). Alternating eluting and non-eluting fibers provide a variance in the longitudinal direction such that the

pharmaceutically active substance exhibits predetermined locally different elution characteristics because each fiber exhibits a different elution characteristic when a longitudinal cut is made though the stent. Therefore parallel *longitudinal* fibers sill exhibit a variance in the longitudinal direction of the stent.

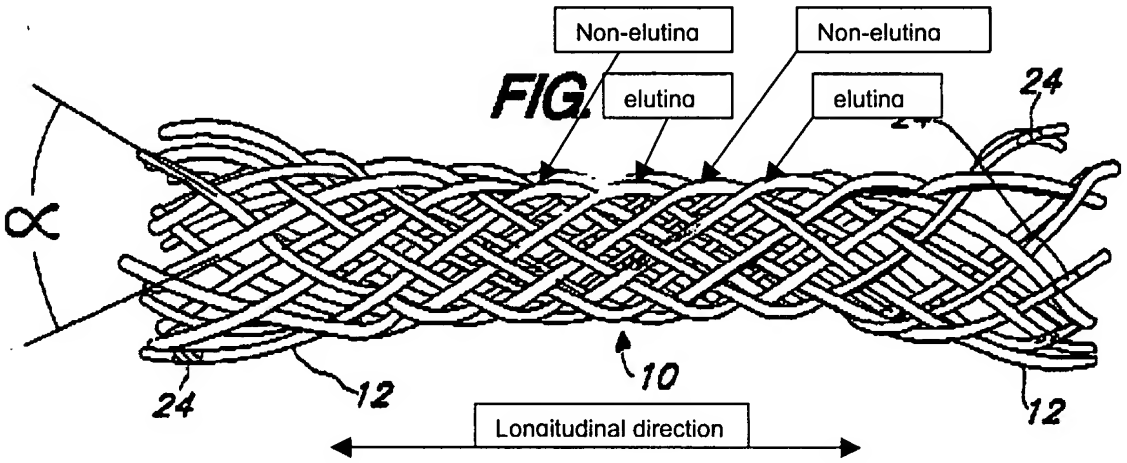


FIG.

Examiner disagrees with the applicants assertion that in order to deliver a variable concentration in the longitudinal direction of the stent, the filaments of Wolff would be required to vary along their length, for the same reasons as presented above.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) The invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims **1-3** are rejected under 35 U.S.C. 102(b) as being anticipated by Wolff et al. (WO 91/12779).

6. Wolff discloses a stent with a coating of a polymer carrier and a pharmaceutically active substance (fig. 1 and pg. 10 lines 38). The concentration of the substance is predetermined in the longitudinal direction such that the implant exhibits predetermined locally different elution characteristics in the longitudinal direction (pg. 11 lines 9-26). (Examiner is considering weaving non-drug eluting strands with drug eluting strands to be a variance in concentration of the drug along the longitudinal direction of the stent). The polymer carrier can be biodegradable and the degradation behavior of the polymer changes local elution characteristics (pg. 12 lines 16-22).

7. Claims 6-7,**9-14** are rejected under 35 U.S.C. 102(e) as being anticipated by Sirhan et al. (Pub. No.: US 2003/0083646 A1).

8. Sirhan et al. discloses A stent comprising a tubular basic body open at its face surfaces (fig. 3), the circumferential wall of which is covered at least in places with a coating system comprising one or more polymer carriers and at least one pharmaceutically active substance (see abstract), whereby the pharmaceutically active substance, after implantation of the stent into a human or animal body, is released into the surrounding tissue (fig. 16-18, for example), wherein a material modification (copolymeric rate controlling element of two polymers with different degradation rates para 34,36) of the at least one carrier (rate controlling elements, para 26-27) varies in the longitudinal direction of the stent (thickness of the rate controlling elements para 34)

so that the pharmaceutically active substance exhibits predetermined locally different elution characteristics in the longitudinal direction of the stent depending on the pathophysiological and/or rheological conditions to be expected of an application. With respect to claim 10, the polymer carrier is biodegradable (para 36). With respect to claim 11, the carrier (rate controlling element) can include an additive which delays enzymatic breakdown of the polymer carrier (for example, copolymers of degradable materials with different degradation rates, para 36). This modification varies in the longitudinal direction due to the different thickness and elution rates desired at each end (para 34).

9. With respect to claims 6-7 and 12-14, Sirhan further discloses a layer thickness (a morphological structure) of the one or more polymer carriers varies in the longitudinal direction of the stent so that the pharmaceutically active substance exhibits predetermined locally different elution characteristics in the longitudinal directional (para 34) The concentration of the pharmaceutically active substance is essentially consistent along the longitudinal direction (para 21, the therapeutic capable agent has a continuous association with a rate controlling element) of the stent and a degradation behavior of the carrier serves to differentiate the local elution characteristics.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff et al. (WO 91/12779) in view of Sirhan et al. (Pub. No.: US 2003/0083646 A1).

12. Wolff is explained supra. However, Wolff does not appear to disclose a higher drug concentration near the face surfaces of the stent than the middle, or the presence of a second drug with a higher concentration in the middle of the stent than the ends. Sirhan teaches higher drug concentrations near the face surfaces of the stent (para 34). Sirhan further teaches the ability to provide multiple drugs in distinct locations along a stent (para 34, multiple rate controlling elements each with separate drugs). Therefore it would have been obvious to one of ordinary skill in the art to modify the prosthesis of Wolff to include the only the end fibers (near the face surfaces) as drug eluting fibers for the purpose of providing drug elution at the ends of the stent, as taught by Sirhan. It would have been obvious to one of ordinary skill in the art to locate the drug eluting fibers of Wolff towards the end (near the face surfaces) using motivation derived from Sirhan, the motivation being: providing different drug elution characteristics near the face surfaces of a stent (para 34). It would have further been obvious to one of ordinary skill in the art to provide another therapeutic agent in the middle section of the stent, because Sirhan teaches the ability to provide multiple adjacent rate controlling elements with multiple therapeutic agents (para 34). One of ordinary skill in the art would have been able to predict the results of such a modification, and further such a modification would have occurred using known methods.

13. Claims 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al. (Pub. No.: US 2003/0083646 A1) in view of Johnson (U.S. Pat. No. 5972027).

14. Sirhan is explained supra. However, Sirhan does not appear to disclose porosity of a polymeric carrier varying along the longitudinal direction of the stent. Johnson teaches a variable porosity stent (fig. 5) for the purpose of delivering different sized therapeutic agents to the body (col. 4 lines 46-50). Therefore it would have been obvious to one of ordinary skill in the art to modify the stent of Sirhan with the teaching of Johnson to include variable porosity along the length of the stent for the purpose of delivering separate therapeutic agents to the body. Such a modification would have occurred using known and ordinary methods, and the results of such a modification would be fully predictable to one of ordinary skill in the art.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suba Ganesan whose telephone number is 571-272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SDG 9/24/2007

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

Brian E Pellegrino